EXHIBIT 3

BRIEF REPORT

Patterns and Trends in Food Portion Sizes, 1977-1998

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Context While general consensus holds that food portion sizes are increasing, no empirical data have documented actual increases.

Objective To determine trends in food portion sizes consumed in the United States, by eating location and food source.

Design, Setting, and Participants Nationally representative data from the Nationwide Food Consumption Survey (1977-1978) and the Continuing Survey of Food Intake by Individuals (1989-1991, 1994-1996, and 1998). The sample consists of 63 380 individuals aged 2 years and older.

Main Outcome Measure For each survey year, average portion size consumed from specific food items (salty snacks, desserts, soft drinks, fruit drinks, french fries, hamburgers, cheeseburgers, pizza, and Mexican food) by eating location (home, restaurant, or fast food).

Results Portion sizes vary by food source, with the largest portions consumed at fast food establishments and the smallest at other restaurants. Between 1977 and 1996, food portion sizes increased both inside and outside the home for all categories except pizza. The energy intake and portion size of salty snacks increased by 93 kcal (from 1.0 to 1.6 oz [28.4 to 45.4 g]), soft drinks by 49 kcal (13.1 to 19.9 fl oz [387.4 to 588.4 mL]), hamburgers by 97 kcal (5.7 to 7.0 oz [161.6 to 198.4 g]), french fries by 68 kcal (3.1 to 3.6 oz [87.9 to 102.1 g]), and Mexican food by 133 kcal (6.3 to 8.0 oz [178.6 to 226.8 g]).

Conclusion Portion sizes and energy intake for specific food types have increased markedly with greatest increases for food consumed at fast food establishments and in the home.

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ALTHOUGH GENERAL CONSENSUS holds that food portions have been increasing and that this increase is one factor contributing to the obesity epidemic in the United States, no empirical data to date have documented actual increases.[1] One recent study showed that most commonly available food portions exceeded the US Department of Agriculture (USDA) and Food and Drug Administration (FDA) standard portion sizes and that most foods are available in larger portion sizes than they were in the 1970s.[2] Another small study reported portion size increases for meat portions but not for other foods, whereas 2 studies have linked portion size increases to increased total energy intake.[3-5] The portion size changes are part of the "supersizing" phenomenon seen at fast food establishments and at restaurants.[6]

In this study, we used nationally representative dietary intake data to determine patterns and trends in portion sizes by type of food and eating location and to compare portion sizes eaten outside the home with those eaten at home.

METHODS

This study used data on individuals aged 2 years and older from 3 nationally representative surveys of the US population (N=63 380): 29 695 for the National Food Consumption Survey 1977 (NFCS77)[7] and 14 658 for the Continuing Survey of Food Intake for Individuals 1989 (CSFII89)[8] and 19 027 for 1996 (CSFII96).[9] The CSFII96 survey also included a sample of children aged 2 to 9 years surveyed in 1998, which was designed to be merged with the CSFII96.

The USDA surveys from 1977 and 1989 contained stratified area probability samples of noninstitutionalized US households in the 48 contiguous states, and the 1996 survey included samples from all 50 states. All 3 surveys were self-weighting and multistage. The sample weights compensate for unequal selection probabilities and nonresponse as well as sampling variability, and these were designed to achieve the specified sample sizes for various sex-age-income domains. Each survey year and the combination of the multiyear surveys were designed to be nationally representative. Detailed information about each survey has been published previously.[7-9]

The NFCS77 and CSFII89 surveys collected 1 day of food intake by in-home, interviewer-administered, 24-hour recall and 2 days of self-administered, 1-day food records. The CSFII96 collected 2 nonconsecutive, interviewer-administered, 24-hour food recalls approximately 10 days apart by telephone. For each food consumed, the respondent was asked whether the eating occasion was a meal or a snack and where the food was obtained. If the food was bought in a store, the respondent was asked whether the food was

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Table 1. Trends in Energy Intake by Eating Location and Key Food for Americans Aged 2 Years and Older[12*]

	Total Energy Consumed			Energy in Meals Consumed			Energy in Snacks Consumed		
	1977-1978	1989-1991	1994-1996	1977-1978	1989-1991	1994-1996	1977-1978	1989-1991	1994-1996
Key foods, %†	18.1	23.6	27.7	14.3	19.7	22.8	46.4	51.0	50.8
At home, %	76.9‡§	72.6‡‖	64.5§‖	77.0‡§	72.3‡‖	63.8§‖	76.0‡§	74.8‡‖	67.4§‖
Total energy, kcal	1791§	1795‖	1985§‖	1588‡§	1559‡‖	1634§‖	203‡§	236‡‖	351§‖

*Adjusted for age, sex, education level, race/ethnicity, region, urban classification, household size, and percentage at poverty level.
†Combined percentage that salty snacks, desserts, soft drinks, fruit drinks, french fries, hamburgers, cheeseburgers, pizza, and Mexican food contribute to that segment of the diet.
‡A significant difference between 1977-1978 and 1989-1991, $P \leq .01$.
§A significant difference between 1977-1978 and 1994-1996, $P \leq .01$.
‖A significant difference between 1989-1991 and 1994-1996, $P \leq .01$.

brought into the home and if so, whether it was eaten at home. These data were then used to classify food sources into the 4 following categories: (1) eaten or prepared at home, (2) from a fast food establishment, (3) from a restaurant, or (4) from any other source. Other than food that was bought from a store, food from any other source was considered to be from that source even if brought into the home.

To examine the thousands of foods contributing to energy intake, the food-grouping system[10] from the University of North Carolina at Chapel Hill was used in this study. This system aggregates all foods in the USDA nutrient composition tables into 74 descriptive and nutrient-based subgroups. In addition, selected popular foods, such as pizza, hamburgers, and french fries, were identified to examine trends in energy intake over time. These foods had been identified in a previous study that examined trends in fat intake.[11]

The foods chosen for this study were those identified as having the greatest kilocalorie changes in Americans' diets between 1977 and 1996.[12] These key foods combined represented 18.1% of all kilocalories consumed in 1977-1978 and represented 27.7% of all kilocalories consumed in 1994-1996 for Americans aged 2 years and older (TABLE 1). While 77% of total kilocalories were consumed at home in 1977-1978, this decreased to 65% of total kilocalories consumed at home in 1994-1996 for Americans aged 2 years and older. During this same period, meals have decreased from approximately 89% of total kilocalories consumed to 81% of kilocalories consumed, and snacks have increased by those 7 percentage points for Americans aged 2 years and older.[12] As previously reported, intakes of medium-fat and high-fat beef and pork products and high-fat luncheon meats and hot dogs have decreased, probably related to increasing amounts of cheeseburgers, pizza, and Mexican food being consumed, and this is consistent with a shift from medium-fat and high-fat meat items to medium-fat and high-fat mixed grain dishes.[13]

The USDA data show each food item consumed, along with the self-reported eating occasion and the self-reported location where food was obtained and eaten. For each survey year, the average consumption of selected food categories (ie, salty snacks, desserts, soft drinks, fruit drinks, hamburgers, cheeseburgers) and other selected food groups (ie, pizza, Mexican food) and the eating location (ie, at home, restaurant, fast food establishment) were determined for each of the following age groups: 2 to 18 years, 19 to 39 years, 40 to 59 years, and 60 years and older). The food category salty snacks included crackers, potato chips, pretzels, puffed rice cakes, and popcorn. The food category desserts included ice cream, pies, cakes, and cookies. Mexican food included burritos, enchiladas, tacos, tostadas, and similar products.

Food consumption was estimated in 2 ways: as energy intake in kilocalories and amount consumed in ounces (0.035 oz = 1.0 g). Average portion sizes were calculated using reported portion sizes of each food at 1 meal or snack. Food models are used to assist respondents in identifying the size of a portion. However, there is wide variability in reported portion size, that is, based on individual specification of amount consumed. These data do not reflect cumulative amount of foods consumed by individuals during the course of a day because these data were examined on an individual meal basis. Thus, these were per-consumer averages, not per capita averages, and were intended to show changes over time in the average portion size for those who consume a specific item, not that the number of individuals consuming an item has changed. All analyses used the 1994-1996 updated nutrient database.[10] To test for statistical differences, SAS version 8.1 (SAS Institute Inc, Cary, NC) and SUDAAN 7.5.6 (Research Triangle Park, NC) software packages were used, which also allowed for weights and control of sample design effects. $P \leq .01$ was set for statistical significance.

RESULTS

Between 1977 and 1996, portion sizes and energy intake increased for all key foods (except pizza) at all locations examined for the total US population aged 2 years and older surveyed (TABLE 2). During this 19-year period, the quantity of salty snacks increased by 93 kcal (0.6 oz), soft drinks by 49 kcal (6.8 oz), hamburgers by 97 kcal (1.3 oz), french fries by 68 kcal (0.5 oz), and Mexican dishes by 133 kcal (1.7 oz).

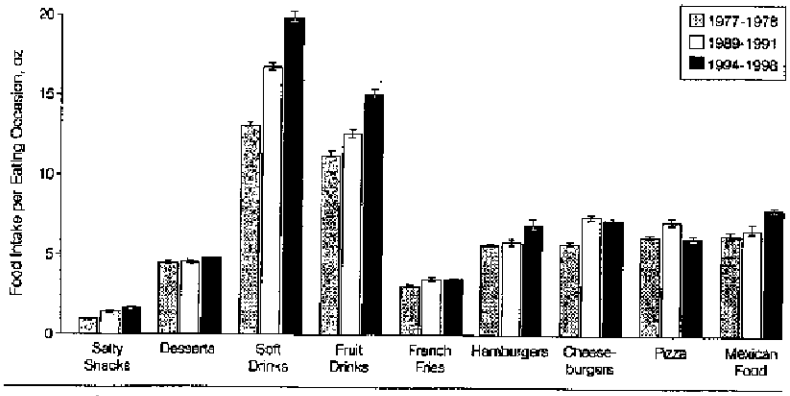
Portion sizes of certain foods increased more than others. Between 1977 and 1996, the average energy intake and portion size of salty snacks increased from 132 to 225 kcal (1.0 to 1.6 oz); the average soft drink consumed increased from 144 to 193 kcal (13.1 to 19.9 fl oz), and the average cheese-

Table 2. Trends in Energy Intake and Portion Size of Key Food Items and by Eating Location for Americans Aged 2 Years and Older*

	Home			Restaurant			Fast Food			Total		
	1977-1978	1989-1991	1994-1996	1977-1978	1989-1991	1994-1996	1977-1978	1989-1991	1994-1996	1977-1978	1989-1991	1994-1996
Energy Intake, kcal												
Salty snacks	127†‡	189†§	206‡§	113‡	150	178‡	160‡	185	249‡	132†‡	199†§	225‡§
Desserts	302‡	315	324‡	259‡	280	306‡	277†	331†	302	316†‡	334†§	357†§
Soft drinks	130‡	133§	158‡§	125‡	126§	155‡§	131†‡	143†§	191‡§	144†‡	157†§	183‡§
Fruit drinks	137†‡	149†§	181‡§	133‡	125§	201‡§	147‡	135§	210‡§	139†‡	152†§	189‡§
French fries	196†‡	240†	236‡	168†‡	229†	222‡	271†‡	260†§	284‡§	188†‡	247†	256‡
Hamburgers	390	397	609	362	335	362	419‡	414§	497‡§	388‡	392§	486‡§
Cheeseburgers	405‡	465	542‡	381	425	485	406‡	564†	537‡	397†‡	544†	533‡
Pizza	493†	591†§	506§	628	671	616	538	603§	603§	487†	556†§	476§
Mexican food	452‡	509	559‡	396	448	495	410‡	431§	594‡§	408‡	446§	541‡§
Portion Size, oz												
Salty snacks	1.0†‡	1.4†§	1.5‡§	0.8‡	1.1	1.3‡	1.2‡	1.3§	1.9‡§	1.0†‡	1.4†§	1.6‡§
Desserts	4.2	4.2	4.4	4.0	4.3	4.5	3.9†‡	4.7†	5.2‡	4.5‡	4.5	4.8‡
Soft drinks	12.2†‡	14.7†§	17.0‡§	10.8†‡	13.6†§	15.7‡§	10.9†‡	14.0‡§	17.7†§	13.1†‡	16.8†§	19.9‡§
Fruit drinks	11.3†‡	12.4†§	14.7‡§	9.7‡	9.5§	14.4‡§	10.4‡	11.8§	15.4‡§	11.3†‡	12.6†§	15.1‡§
French fries	3.6†	4.2†	3.9	2.3†‡	3.1†	3.1‡	2.1†‡	3.0†§	3.3‡§	3.1†‡	3.5†	3.6‡
Hamburgers	5.7	5.7	8.4	5.3	4.9	5.0	6.1‡	6.3	7.2‡	5.7‡	5.9§	7.0‡§
Cheeseburgers	5.8‡	6.4	7.4‡	5.5	5.7	6.8	5.9†‡	7.7†	7.3‡	5.8†‡	7.4†	7.3‡
Pizza	6.2†	7.6†§	6.5§	7.9	7.4	6.8	6.8	7.8§	6.5§	6.2†	7.1†§	6.1§
Mexican food	7.1	7.4	8.3	6.0‡	7.0	7.9‡	6.0‡	6.7	8.2‡	6.3‡	6.7§	8.0‡§

*Weighted to be nationally representative for each time period. To convert ounces to grams, divide by 0.035, and to convert fluid ounces to milliliters, multiply by 29.57.
†A significant difference between 1977-1978 and 1989-1991, $P \leq .01$.
‡A significant difference between 1977-1978 and 1994-1996, $P \leq .01$.
§A significant difference between 1989-1991 and 1994-1996, $P \leq .01$.

Figure 1. Portion Sizes for Selected Key Food Items for Americans Aged 2 Years and Older, 1977-1996



Error bars indicate SE.

burger from 397 to 533 kcal (5.8 to 7.3 oz) (Table 2 and FIGURE 1).

Overall portion sizes for all of the selected foods, other than pizza, increased. There were no differing trends within age groups that were statistically significant; however, there are age group differences, particularly for the 60-year-olds. For people aged 2 to 18 years, hamburger portion sizes in restaurants decreased. For people aged 60 years and older, portion sizes for soft drinks decreased. Additional information for specific age groups can be obtained from the authors.

In 1994-1998, the largest portion sizes for most foods were found at fast food establishments, including salty snacks, soft drinks, fruit drinks, french fries, and Mexican food (Table 2 and FIGURE 2). For desserts, hamburgers, and cheeseburgers, the largest portion sizes were found at home. Consistently, restaurant portion sizes were smaller across all key foods except pizza.

COMMENT

This study provides evidence to support the general consensus that there is a marked trend toward larger portion sizes in the United States. Between 1977 and 1996, both inside and outside the home, portion sizes increased for salty snacks, desserts, soft drinks, fruit drinks, french fries, hamburgers, cheeseburgers, and Mexican food. Pizza portions in general decreased during this period. The size of the increases are substantial. Since an added 10 kcal per day of unexpended energy is equivalent to an extra pound (0.45 kg) of weight per year, it is easy to see the potential impact of large increases in portion sizes that ranged from 49 to 133 kcal (0.3 to 1.7 oz in weight; 3.8 to 6.8 fl oz) per item for com-

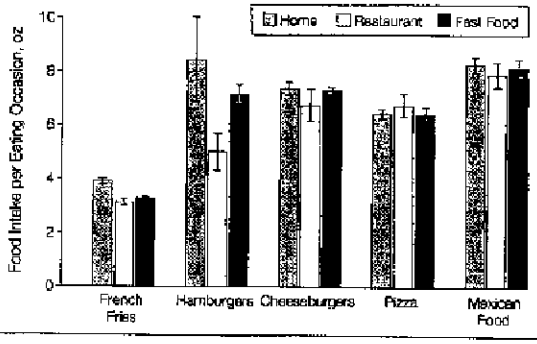
monly consumed items, such as salty snacks, soft drinks, hamburgers, french fries, and Mexican food.

Some potential limitations of our study are that the USDA changed its methods for collecting dietary data[14,15] and that persons who are overweight most likely underreport their energy intake,[14-18] with the extent of underreporting having increased over time.[19] There is no information to date in the United States to indicate systematic bias in reporting by eating location. Furthermore, due to increasing underreporting, the estimates of portion size are most likely smaller than the actual portion sizes being consumed. Thus, we believe that the trends in eating behavior highlighted in this article are representative of those occurring among the US population. The USDA is no longer conducting its survey; the last one conducted was the CSFII96. The survey has been combined with the National Health and Nutrition Examination Survey[7-9] and currently there are no comparable data. The next comparable data set is being collected in 2002-2003. The data presented are most likely underestimations of current portion sizes.

Our study also identifies salient differences in portion size by food location. For most of the selected foods, fast food establishments served the largest and restaurants the smallest portion sizes. This might relate to fast food establishments' pricing practices of "value adding" whereby they offer much larger portions for a minor cost increase, and in some cases it is less expensive to eat larger portions in value packages than smaller portions. At the same time, the most surprising result is the large portion size increases for food consumed at home—a shift that indicates marked changes in eating behavior in general.

These findings suggest that the public requires better education about control of portion size both inside and outside the home. Simply educating the public about which foods to eat or not to eat is not enough, as an equally important issue is the quantity of food being consumed. While the exact contribution of portion size changes to the increases in US overweight and obesity rates cannot be determined, the prevalence of adult obesity has increased from 14.5% in 1971 to 30.9% in 1999.[20] The results of this study indicate that control of portion size must be systematically addressed both in general and as it relates to fast food pricing and marketing. The best way to encourage people to eat smaller portions is if food portions served inside and outside the home are smaller. However, this change in behavior may be difficult to achieve due to the US advertising climate and its influence on the public.

Figure 2. Portion Sizes for Selected Food Items Consumed by Eating Location for Americans Aged 2 Years and Older, 1994-1998



Error bars indicate SE.

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Analysis and interpretation of data: Nielsen, Popkin.
Drafting of the manuscript, statistical expertise, and administrative, technical, or material support: Nielsen.
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EXHIBIT 4

GROCERY MANUFACTURERS OF AMERICA
MAKERS OF THE WORLD'S FAVORITE BRANDS OF FOOD, BEVERAGES, AND CONSUMER PRODUCTS

June 18, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
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Rockville, MD 20852

ANPR COMMENTS

Re: Docket No. 2003N-0076; Food Labeling: *Trans* Fatty Acids in Nutrition Labeling; Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements; Reopening of the Comment Period; 69 Fed. Reg. 9559 (Mar. 1, 2004)

The Grocery Manufacturers of America (GMA)[1] appreciates this opportunity to offer comments concerning the Food and Drug Administration (FDA) Advance Notice Proposed Rulemaking (ANPR) on *trans* fatty acids in nutrition labeling. This ANPR seeks comments on potential approaches to establishing a daily value (DV) for *trans* fat and a revised DV for saturated fat, qualifying criteria for nutrient content and health claims, and the use of possible footnote or disclosure statements about *trans* fat.

Summary

GMA urges FDA to address *trans* fat labeling as part of a deliberate, reasoned, and comprehensive strategy that will best achieve the public health goals associated with such labeling. The National Academy of Sciences/Institute of Medicine (IOM/NAS) has recommended that FDA establish a joint daily value (specifically, a daily reference value) for *trans* fat and saturated fat by using "food composition data, menu modeling, and data from dietary surveys to estimate minimum intakes consistent with nutritionally adequate and health-

[1] GMA is the world's largest association of food, beverage and consumer product companies. With U.S. sales of more than $500 billion, GMA members employ more than 2.5 million workers in all 50 states. The organization applies legal, scientific and political expertise from its member companies to vital food, nutrition and public policy issues affecting the industry. Led by a board of 42 Chief Executive Officers, GMA speaks for food and consumer product manufacturers and sales agencies at the state, federal and international levels on legislative and regulatory issues. The association also leads efforts to increase productivity, efficiency and growth in the food, beverage and consumer products industry.

promoting diets for diverse populations."2 Regardless of the framework that is pursued, however, evaluation of a possible DV for *trans* fat raises complex and novel issues that will require considerable agency resources and thought, as well as significant public participation. Significantly, neither the Nutrition Subcommittee of the FDA Food Advisory Committee ("Nutrition Subcommittee") nor the 2002 IOM/NAS Panel on Macronutrients was able to identify a quantitative recommended intake for *trans* fat consumption, illustrating the difficulty presented by *trans* fat. 3/

To achieve the public health goals that *trans* fat labeling is intended to attain, proper sequencing and timing are key. GMA urges FDA to focus on, in this order, the following initiatives: (1) proper implementation of the final rule on quantitative *trans* fat labeling, (2) regulatory initiatives that will help drive product reformulation to reduce *trans* fat, and (3) a thoughtful and comprehensive review of the Nutrition Facts panel.

Regarding nutrient content claims, GMA supports the establishment of "*trans* fat free" and "reduced *trans* fat" claims. GMA also urges FDA to re-evaluate disqualifying requirements for health claims. GMA intends to address disqualifying and minimum nutrient content requirements in greater detail in comments that will be submitted in response to the agency's May 4 notice concerning general principles for health claims.4

First Priority: Fully Implement Quantitative *Trans* Fat Labeling

To assist consumers now, and to follow through on what is already required, GMA urges FDA to first focus on informing consumers about quantitative *trans* fat labeling (together with saturated fat and cholesterol). Both agency and industry efforts to educate the public about *trans* fat are in progress and must receive adequate resources and attention.

An immediate focus on quantitative *trans* fat labeling is needed because mandatory labeling of a daily value for *trans* fat (in any form) is—even under the best of circumstances—likely to be several years away. The July 2003 final rule requiring the declaration of quantitative *trans* fat values in the Nutrition Facts box will take effect on January 1, 2006, and industry efforts to comply with this major change are substantially underway.5 Thus, even if FDA were to issue a

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2 IOM/NAS, *Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification*, at 5-13 (Dec. 2003).

3/ *See* Transcript of Food Advisory Committee, Nutrition Subcommittee Meeting, Total Fat and Trans fat (Apr. 27-28, 2004); IOM/NAS, *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids* (the "Macronutrient Report") (Nat'l Academy Press 2002).

4 69 Fed. Reg. 24541 (May 4, 2004).

5 If FDA were to issue a proposal and final rule this year, so as to finalize a daily value rule in time for the January 1, 2006 uniform compliance date, a significant economic burden would be presented because so many labels are already too far in the development pipeline to be pulled back and further revised efficiently.

proposal this year and a final rule just a year later, the effective date would not be until January 1, 2008. Moreover, the complexity and novelty of this issue suggest that several years, at a minimum, would be required to see any rulemaking through to completion. For these reasons, GMA believes that any additional labeling requirements for *trans* fat realistically could take effect, at the earliest, in 2008.

An immediate focus on quantitative labeling is therefore prudent and offers FDA's best opportunity to ensure that consumers are educated about *trans* fat. This includes providing consumers with information about what *trans* fat is, what products may contain it, and how to make health-conscious food selections within the context of a food's total nutritional profile. Part of this effort should include a cautionary note that it is overly simplistic to rely upon the word "hydrogenated" in the ingredients list as an indication of whether *trans* fat is present in the food at dietarily significant levels. Many products that contain partially hydrogenated oils contain these ingredients at extremely low levels that do not rise to nutritional significance; other products contain fully hydrogenated oils (e.g., high stearate soybean oils) that not only do not contain *trans* fat, but also contain saturated fat in the form of stearic acid, which a substantial body of evidence suggests is cholesterol neutral. GMA also recommends that information on stearic acid be included in agency educational materials.

Second Priority: Focus on Product Reformulation

Second, FDA should focus on labeling initiatives that will best drive product reformulation to reduce *trans* fat content, and should allow adequate time for reformulation to occur, before considering a DV for *trans* fat in any form. FDA's own economic analysis accompanying the *trans* fat rulemaking identified product reformulation as a linchpin for public health goals to be derived from *trans* fat labeling. GMA believes strongly, however, that any new or reformulated products need to be healthier than the products they replace. The call for "zero" *trans* fat heard in some circles would very likely lead to unintended negative consequences, such as significantly increased saturated fat content in some products, if industry is not allowed sufficient time to reformulate.6/

Reformulation. The reformulation process does not come without significant product development challenges. *Trans* fats cannot simply be removed from products; they must be replaced with another ingredient that carries similar qualities (e.g., texture, structure, taste, shelf stability, etc.) in order to maintain product integrity. Even if a promising substitute for a *trans* fat-containing ingredient is found, it must be assessed as part of a complex evaluation process that requires substantial research and development work, sensory evaluation, in-plant modifications, adjustments, and scale-up efforts, stability studies, and packaging and labeling modifications, among other steps in the product development process.

GMA has prepared a preliminary summary of a "typical" product reformulation process (see Appendix B). If all goes well, a "typical" process can require several years, thousands of personnel hours, and millions of dollars. For example, Frito-Lay North America, Inc. reported

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6/ This concern is addressed more fully in our comments of May 26, 2004, which are incorporated herein and attached for your reference in Appendix A.

that reformulation of its snack food lines to remove *trans* fat required approximately three years, 7000 personnel hours, 240 analytical tests, 25 consumer tests, and tens of millions in capital expenditures. Of course, if challenges are encountered, such as consumer rejection of a proposed reformulation, additional time and expense would be required. Industry is committed to pursuing alternatives to *trans* fats, but must be allowed sufficient time to pursue these alternatives in a meaningful way.

Adequate time for reformulation is also important because any process for establishing a DV requires consideration of current and likely *trans* fat intake. The *trans* fat content of the food supply is in a period of rapid and significant change, and these changes should be encouraged and allowed to bear fruit.7 Companies should be encouraged to expend their limited resources on product reformulation that improves public health over the long term, rather than on label changes that likely will need to be changed again in the near future.

By allowing adequate time for reformulation, FDA can also ensure that adequate *trans* fat data will be available, should the agency decide to consider the approach recommended by the IOM/NAS for establishing a DV. As the final rule on quantitative *trans* fat labeling has not yet taken effect, food composition data on *trans* fat are increasing, but remain limited. If the recommended IOM/NAS approach is to be meaningfully pursued, consideration of minimum intakes must take into account a diversity of circumstances, including dietary differences due to cultural, regional, socioeconomic, and other demographic considerations. The intake assessment necessary to carry out the recommended IOM/NAS approach, therefore, cannot be adequately pursued without data on *trans* fat levels for a wide variety of foods. GMA believes that such data are not currently available, and that a focus on reformulation now and in the near future would also allow time for the necessary data to be developed.

Labeling. GMA urges FDA to pursue labeling initiatives that will aid reformulation efforts and provide incentives for the use of healthful fats and oils. Two labeling issues warrant special consideration: (1) a separate and voluntary declaration of stearic acid, a cholesterol-neutral saturated fat, in the Nutrition Facts panel and elsewhere on the label, and (2) development of appropriate and flexible claim criteria for claims such as "*trans* fat free."

Since FDA last evaluated the state of the science, stearic acid has been widely recognized as a "neutral" fatty acid that does not raise low density lipoprotein (LDL) cholesterol. Of particular importance to this rulemaking, stearic acid was recognized as cholesterol-neutral during the deliberations of the April 27 to 28 meeting of the Nutrition Subcommittee. 8/ In 2002, stearic acid was similarly identified as cholesterol-neutral in the IOM/NAS "Macronutrient Report," which described stearic acid as more similar to oleic acid than to palmitic, lauric, or myristic

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7 Examples of some of the many improvements in our member company products can be found in the May 26, 2004 comments provided in Appendix A. These examples almost certainly represent a fraction of the forthcoming formulation changes, as GMA understands that many companies plan to reformulate but have not yet made these plans public. GMA members would be pleased to meet with the agency to discuss these examples and associated resources if that would be useful.

8/ *See, e.g.*, Transcript of Food Advisory Committee, Nutrition Subcommittee Meeting, Total Fat and Trans fat (Apr. 27-28, 2004) (statements of A. Lichtenstein).

acids. 9/ Moreover, since 1993, the regulations of the Food Safety and Inspection Service (FSIS) have permitted the voluntary declaration of stearic acid in nutrition labeling for meat and poultry products. 10/ These developments provide a reasonable basis for FDA to reconsider its position on this important fatty acid.

Despite the well-recognized status of stearic acid as neutral with respect to LDL cholesterol, the current nutrition labeling regulations do not facilitate its identification and use. Indeed, under the present regulations, stearic acid is silently included within the quantitative declaration and daily value for saturated fat—a result that arguably fails to allow consumers to "readily observe and comprehend such information and to understand its relative significance in the context of the total daily diet." 11/ To facilitate healthful reformulation and replacement of *trans* fat with alternatives like stearate-rich fats and oils, GMA asks that FDA allow the voluntary identification of stearic acid within nutrition labeling. GMA believes that the public health would benefit from inclusion on a voluntary basis of a separate line for stearic acid in the Nutrition Facts panel, as a subset of saturated fat. This declaration should be accompanied by the quantitative amount of stearic acid per serving, without a separate DV.

GMA also believes that public health would benefit from development of appropriately flexible and obtainable claim criteria for nutrient content claims, such as "*trans* fat free." Although many reformulation efforts are currently underway, flexible claim criteria are critical to encourage further reformulation work that will affect a broad cross-section of the food industry. Flexibility is needed because many ingredients that provide the functionality of *trans* fat may also contain higher levels of saturated fat.

Our member companies are investing human and monetary resources with the fats and oils industry in an effort to find alternative ingredients that reduce or eliminate *trans* fat without increasing saturated fat or with only a minimal increase in saturated fat. At this time, however, it is simply unrealistic to expect that increases in saturated fat can be entirely avoided. So long as these smaller increases in saturated fat do not offset the health benefits of reduced *trans* fat levels, and reformulated products are healthier overall, they should not preclude the use of claims like "*trans* fat free" that can provide incentives for widespread reformulation. GMA's specific proposals for "*trans* fat free" and similar claims that GMA believes will promote reformulation are discussed more fully under a separate Nutrient Content Claims heading below.

Third Priority: Cohesive Review of Nutrition Facts Panel

Third, FDA should dedicate resources to a thoughtful, efficient, and cohesive review of the Nutrition Facts panel. For the first time since enactment of the Nutrition Labeling and Education Act of 1990 (NLEA), FDA is embarking upon a major review of nutrition labeling requirements. This review is prompted not only by the need to update labeling to reflect the latest dietary

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9/ IOM/NAS Macronutrient Report, *supra* note 3, Ch. 8, 11.

10/ 9 C.F.R. §§ 317.309(c), 381.409(c).

11/ *See* Nutrition Labeling and Education Act of 1990, § 2(b)(1)(A).

recommendations, as set forth in the IOM/NAS dietary reference intakes (DRIs), but also by current initiatives regarding obesity. The DV concept is a critical component of this review, and efficiency dictates that DV issues be considered and addressed as part of a single, comprehensive, and cohesive effort. FDA should not—and from an economic perspective, must not—undertake this effort in a piecemeal fashion. Too frequent changes to the familiar Nutrition Facts panel could also conceivably erode consumer confidence in the food label.

As part of this review, FDA should develop a strategy for educating consumers about the DV concept. Educating consumers about the DV concept is important because it would lay the necessary groundwork for, and should be a condition precedent to, adoption of any new or revised DV declaration. A growing body of evidence suggests that consumers are either confused by the DV concept or do not use it, so it is simply premature to pursue a new DV of any type at this time. 12

For the foregoing reasons, it is simply inefficient and premature to adopt a DV for *trans* fat at the present time, either in the form of a joint DV with saturated fat or standing alone. Ensuring public health gains in an efficient manner dictates that a DV for *trans* fat should be considered only as part of the review of other DVs and after the marketplace has had time to make product reformulation. Moreover, at the present time scientific support for a DV is lacking, as neither the Nutrition Subcommittee nor the 2002 IOM/NAS Panel on Macronutrients was able to identify a quantitative recommended intake for *trans* fat consumption.

***Trans* Fat Footnote**

As described in previous comments, GMA also believes strongly that the use of a footnote advising consumers to limit their intake of *trans* fat, saturated fat and/or cholesterol is similarly premature, regardless of the wording selected. As it has for other nutrients that lack a DRV or RDI, FDA should require declaration of the amount of *trans* fat, but leave the Percent Daily Value declaration blank. This approach is sound from both a legal and a policy standpoint because FDA historically has not required a Percent Daily Value declaration where there exist insufficient data to establish a DRV (e.g., monounsaturated fat, sugars) or other reasons make such a declaration unnecessary in certain circumstances (i.e., protein).

GMA continues to believe that a footnote is not needed to provide guidance to consumers when using the quantitative information to help maintain healthy dietary practices. Consumers are learning about *trans* fat through information on manufacturers' web sites as well as the media. FDA has launched their consumer education campaign on *trans* fat, and has developed consumer messages on how consumers can keep their intake of saturated fat, *trans* fat, and cholesterol low. As described previously, GMA believes that FDA should continue to focus on these efforts at the present time, and should plan as next steps changes that will truly help to drive product reformulation, followed by the nutrition labeling review contemplated by the obesity initiative and the recent IOM/NAS report addressing the use of DRIs in food labeling. Adoption of a

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12 *See, e.g.*, Division of Market Studies, Office of Scientific Analysis and Support, FDA CFSAN, Helping Consumers Lead Healthier Lives through Better Nutrition: A Social Sciences Approach to Consumer Information, Food Choices, and Weight Management (Jan. 2004) (Executive Summary).

footnote at the present time would divert limited resources from these important activities and would be of dubious value to consumers.

The Relationship of *Trans* Fat to Nutrient Content Claims

GMA supports the establishment of "*trans* fat free" and "reduced *trans* fat" claims, the inclusion of *trans* fat criteria in claims pertaining to saturated fat, and the continued validity of factual amount claims for *trans* fat, as follows.

"*Trans* fat free." GMA believes that this claim should require, per reference amount and per labeled serving, (1) less than 0.5 g of *trans* fat, consistent with FDA's approach to other "free" claims, and (2) no more than 25% of the total fat as saturated fat, or, if this percentage is exceeded, no more than 2.0 g of total saturated fat.

A limitation of no more than 25% of total fat as saturated fat is necessary to facilitate and encourage the use of healthy oils in product formulations. FDA's initial "*trans* fat free" proposal would have required that products bearing the claim contain less than 0.5 g of saturated fat, the equivalent of "saturated fat free."13 This approach, however, has the undesirable effect of preventing even the healthiest of oils (e.g., olive oil, canola oil), as well as many products formulated with such oils, from bearing "*trans* fat free" claims. This result is unrealistic and unjustified, as all oils contain some amount of saturated, polyunsaturated, and monounsaturated fatty acids. Moreover, a growing body of evidence indicates that appropriate consumption of healthful oils may help to reduce the risk of coronary heart disease, as evidenced by the recent qualified health claim petition on monounsaturated fatty acids from olive oil.14

The proposed 25% criterion is also consistent with the IOM/NAS Acceptable Macronutrient Distribution Range (AMDR) for fat of 20% to 35% of energy. At the midpoint of the AMDR (i.e., 28% of energy), 25% of total fat corresponds to 7% of total energy from saturated fat. In other words, based on a 2000 calorie diet, 28% of energy from fat corresponds to approximately 62 g of total fat; 25% of 62 g is 15.5 g of saturated fat, which corresponds to 7% of total energy from saturated fat. A diet containing 7% of calories from saturated fat is widely considered to be low in saturated fat. GMA believes that the proposed 25% criterion will serve to keep saturated fat in check in a manner consistent with prevailing dietary recommendations while encouraging reformulation of products with healthier oils.

GMA further believes that a 2 g limitation on saturated fat is prudent so as not to penalize products with very little fat (e.g., products with 3 g of total fat, 2 g of which is saturated). A 2 g limitation is consistent with the existing definitions of "cholesterol free" and "low cholesterol" in 21 C.F.R. § 101.62(d), both of which provide that foods bearing these claims may contain no more than 2 g of saturated fat. In adopting these definitions, FDA found a 2 g limit for saturated

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13 64 Fed. Reg. 62746, 62796 (proposed 21 C.F.R. § 101.62(c)(6) (Nov. 17, 1999).

14 The North American Olive Oil Association, Qualified Health Claim Petition, Authorization of a Health Claim for Monounsaturated Fatty Acids from Olive Oil and Coronary Heart Disease (Aug. 28, 2003) (Docket No. 2003Q-0559).

fat to be consistent with dietary recommendations for no more than 10% of calories from saturated fat, and further found that such flexibility would permit a reasonable number of foods, including soybean, corn, and olive oils, to bear "no cholesterol" claims.15 These findings similarly justify a 2 g limitation for saturated fat in the case of "*trans* fat free."

The beneficial impact of the flexible criteria GMA suggests is reflected in the attached chart (see Appendix C), which depicts the eligibility of several products under differing criteria for "*trans* fat free." This chart confirms that a more flexible saturated fat limitation of no more than 2 g or 25% of fat as saturated fat would enable appropriate products to bear "*trans* fat free" claims, providing incentive for manufacturers of these and similar products to reformulate.

Finally, if the term "*trans* fat free" is declared and the product contains a partially hydrogenated ingredient, GMA believes that the manufacturer should use an asterisk in the ingredient statement to inform consumers that the partially hydrogenated ingredient contributes a trivial or insignificant amount of *trans* fat. Informative statements of this type have long been required in the case of other "free" claims, including "fat free" and "sugar free." Based on recent FDA guidance, GMA understands that the agency will not object to the voluntary use of an asterisk in the ingredient statement explaining that a partially hydrogenated ingredient contributes a trivial or insignificant amount of *trans* fat, even if a manufacturer chooses not to make a *trans* fat free claim.

"Saturated fat free." GMA believes that this claim should be comparable to the "*trans* fat free" claim, as saturated fat (with the exception of stearic acid, as noted above) and *trans* fat are anticipated to have similar physiological effects. Accordingly, GMA does not object to maintaining the existing definition of "saturated fat free" in 21 C.F.R. § 101.62(c)(1). This definition requires foods marketed as "saturated fat free" to contain less than 0.5 g of saturated fat and less 0.5 g *trans* fat per reference amount and per labeled serving.

"Reduced *trans* fat" and "reduced saturated fat." GMA urges that the criteria for a "reduced *trans* fat" claim should require a reduction of at least 25% in *trans* fat as compared to an appropriate reference food, consistent with FDA precedent for "reduced saturated fat" in 21 C.F.R. § 101.62(c)(4). To help ensure that reductions in *trans* fat are not negated by attendant increases in saturated fat, and vice versa, GMA recommends that both descriptors include a criterion for the maximum increase in *trans* fat or saturated fat, as applicable, that would be permitted in foods bearing one of these claims. Finally, GMA suggests that both claims include limitations that ensure that any overall reductions will be nutritionally meaningful.

Specifically, for "reduced saturated fat" and similar claims (e.g., "less saturated fat"), GMA recommends that FDA retain the existing definition in 21 C.F.R. § 101.62(c)(4), with the following addition: when saturated fat is decreased, *trans* fat may increase by an amount that is no greater than half (i.e., 50%) of the quantitative decrease for saturated fat. Thus, if saturated fat is reduced from 6 g to 3 g (a 3 g, or 50% reduction), any attendant increase in *trans* fat could not exceed 1.5 g, for a net decrease of 1.5 g, or 25%. This approach ensures that the minimum net decrease in saturated fat and *trans* fat combined will be at least a 12.5% reduction.

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15 58 Fed. Reg. 2302, 2334 (Jan. 6, 1993).

For "reduced *trans* fat" and similar claims, GMA recommends that, based on longstanding agency precedent, a 25% reduction in *trans* fat be required. In addition, to prevent large reductions in *trans* fat content from being negated, GMA believes that no more than half (50%) of the quantitative amount of *trans* fat that is reduced should be offset by gains in saturated fat. Thus, if *trans* fat is reduced from 8 g to 4 g (a 4 g, or 50% reduction), any attendant increase in saturated fat could not exceed 2 g, for a net decrease of 2 g, or 25%. As was the case with saturated fat, this approach ensures that the minimum net decrease in *trans* fat and saturated fat combined will be at least a 12.5% reduction.

GMA further believes that the overall amount of reduction for each nutrient should be nutritionally meaningful. For saturated fat, this is ensured by FDA's restriction that "reduced" claims are not permitted where the reference food meets the definition for "low saturated fat." For *trans* fat, however, there is no definition of "low," so a different criterion needs to be developed.

For *trans* fat, 0.5 g is the smallest increment that may be identified in nutrition labeling, and therefore represents the minimum amount deemed by the agency to be of nutritional significance. Accordingly, GMA believes that, at a minimum, *trans* fat should be reduced by at least 0.5 g in foods bearing reduced *trans* fat claims.

GMA acknowledges that there ideally would be no increase in saturated fat in foods bearing reduced *trans* fat claims; similarly, there ideally should be no increase in *trans* fat in foods bearing reduced saturated fat claims. This ideal, however, is not consistently achievable with current products and technologies. Because small dietary changes can amount, over time, to large differences of public health significance, GMA urges FDA to adopt a flexible approach that will encourage product reformulation.

Disclosure levels. In the 1993 rulemakings to implement the NLEA, FDA required that foods bearing nutrient content claims include disclosure statements regarding fat, saturated fat, cholesterol and/or sodium when such nutrients are present at levels exceeding 20% of the DRV. Because there is no DV for *trans* fat, and because it is premature to establish a DV, for the reasons explained in these comments, GMA believes it is similarly premature to establish a disclosure level for *trans* fat for nutrient content claims. As explained previously, GMA believes that FDA's immediate focus should be on (1) implementing quantitative *trans* fat labeling requirements, (2) pursuing labeling initiatives that will best drive product reformulation, such as defining "*trans* fat free," and (3) undertaking a cohesive review of the Nutrition Facts panel, as part of the agency's plans to incorporate new DRIs in food labeling and address obesity concerns. By focusing on these important initiatives and allowing adequate time for reformulation, FDA will be able to accomplish the greatest good for public health.

Factual statements of Amount. GMA urges FDA to affirm that purely factual statements of amount (e.g., 0 g *trans* fat) are permitted if truthful and not misleading. Such claims are not required to meet any definition of "*trans* fat free" that may be adopted, nor are they prohibited in the absence of a "trans fat free" definition.

Factual statements regarding the amount of a nutrient in a food are "amount or percentage" claims that are not subject to definition pursuant to section 403(r)(1)(A) of the Federal Food, Drug, and Cosmetic Act (FFDCA). Instead, consistent with First Amendment considerations and Congress' direction to allow such claims so long as they are truthful, not misleading, and consistent with defined terms, 16/ FDA has prescribed by regulation the circumstances for using these claims. Under the applicable regulation, set forth at 21 C.F.R. § 101.13(i), amount claims that characterize the level of a nutrient in food (e.g., "less than 3 g of fat") must either be consistent with the definition for a corresponding claim or must include a disclaimer indicating that the food does not meet such a claim (e.g., "only 200 mg of sodium per serving, not a low sodium food.") If, however, an amount claim includes no characterizing terms, the claim is expressly permitted without a disclaimer pursuant to 21 C.F.R. § 101.13(i)(3). Accordingly, purely factual statements regarding the amount of *trans* fat in a food, including "0 g *trans* fat per serving," are authorized pursuant to 21 C.F.R. § 101.13(i)(3) unless they are false or misleading. GMA does recommend that, if a product contains greater than 2 g saturated fat per serving (the level currently allowed in foods permitted to bear "cholesterol free" claims), and does not qualify for a "trans fat free" claim, a referral statement be used in proximity to the amount statement to alert the consumer to the saturated fat content of the product.

The Relationship of *Trans* Fat to Health Claims

Disqualifying levels for health claims generally. FDA should carefully consider use of disclosure levels in place of disqualifying levels currently provided in 21 C.F.R. § 101.14(a). As GMA has commented previously, the principles established in the *Pearson v. Shalala* and *Whitaker v. Thompson* decisions make clear that FDA regulations relating to disqualifying criteria of this type violate First Amendment commercial speech protection. GMA intends to address disqualifying and minimum nutrient content requirements in greater detail in comments that will be submitted in response to the agency's May 4 notice concerning general principles for health claims.17

Disqualifying levels for CHD claims. The saturated fat and *trans* fat content of food are important considerations that should be addressed in the evaluation of health claims pertaining to coronary heart disease (CHD). It is, however, premature to establish a disqualifying level for *trans* fat for CHD health claims because there is no DV for *trans* fat, and it is premature to establish a DV, for the reasons explained in these comments. As for total fat, disqualifying criteria for CHD health claims are unnecessary because, as was recognized by the Nutrition Subcommittee, there is no relationship between total fat intake, per se, and CHD.

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16/ NLEA § 3(b)(1)(A).

17 69 Fed. Reg. 24541 (May 4, 2004).

GMA appreciates FDA's consideration of these comments, and would be pleased to discuss the information and points provided herein upon request.

Sincerely,

Alison Kretser

Alison Kretser, M.S., R.D.

APPENDIX A

GROCERY MANUFACTURERS OF AMERICA
MAKERS OF THE WORLD'S FAVORITE BRANDS OF FOOD, BEVERAGES, AND CONSUMER PRODUCTS

May 26, 2004

Lester Crawford, DVM, Ph.D. (HF-1)
Acting Commissioner
Food and Drug Administration
Room 14-71
Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

Robert E. Brackett, Ph.D. (HFS-1)
Director
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

Dear Dr. Crawford and Dr. Brackett,

I am writing to bring your attention to the key element in the public discussion about trans fatty acids (trans fat), namely the reduction or elimination of trans fat in processed foods. Our members in the food industry take the public concerns about trans fat seriously, and are working diligently to address these concerns.

The food industry has made great strides in its efforts to reformulate products to lower trans fatty acids levels by reducing or eliminating the partially hydrogenated vegetable oil content in the food supply. However, we believe strongly that any new or reformulated products need to be healthier than the products they replace, and that the call for mandatory "zero" trans fat heard in some quarters could lead to unintended consequences.

Saturated fat consumption remains a public health concern. A removal of trans fat "at any cost" could lead to a return to oils with high saturated fat content and products that have a less healthy fat profile than the products they are intended to replace. Therefore, we call upon FDA to adopt policies that foster the development of healthier products for American consumers and not focus on only one element of the overall nutritional profile. Let me elaborate briefly with three simple points:

Point 1: The processed food industry is addressing trans fat in a serious way.

The processed food industry has always responded to newer scientific evidence and the resultant regulatory policies. Since last summer, our member companies have been revising their nutrition labels to add quantitative labeling of trans fat in accordance with new FDA regulations. We also strongly support the FDA's educational efforts to inform consumers about the role of trans fat, saturated fat and cholesterol in proper dietary management.

GMA members, working in tandem with the fats and oil industry, have also made considerable R&D investments in finding alternative ingredients that reduce or eliminate trans fat without increasing saturated fat in any significant way. These R&D efforts seek to merge the health benefits of alternative ingredients with necessary functional elements such as taste, texture, structure, and shelf stability. Equally important is evaluation of product performance differences in the reformulated products as is or as ingredients for recipe use applications in the home.

It should be noted that removing trans fat does not come without challenges. Some of these, such as reformulation to achieve the same taste, appearance, stability and performance, are widely known. Less understood are challenges in sourcing replacement ingredients, availability in commercial quantities, adjustments to equipment to receive, store and use alternative ingredients, and adjustments to cooking, handling and packaging, with resulting impacts on efficiency and productivity.

Point 2: The food industry's guiding principle for reformulation is that any new, reformulated product needs to be healthier than the product it replaces.

It is a cardinal principle that we always want to be taking a step forward, not a step back. Accordingly, whenever possible, we believe that any new or reformulated products need to have improved fatty acid profiles than the products they replace. This means we must look at the total amount of fatty acids in the product and not focus exclusively on trans fat content. The goal should be that any decreased levels of trans fat should be replaced with no increase or with as small an increase in saturated fat as possible, and at most by an equivalent increase in saturated fat, in as many product categories as technologically feasible.

It is also essential that food companies take the time needed to "get it right" so that product evolution is responsible and responsive to today's health concerns. Our members have been vigorously pursuing this goal, and have already made significant progress in a short period of time. Examples of some of these improvements can be found in Appendix A1. Given this commitment, with time and a devoted R&D effort, we will see an increase in the introduction of products with more favorable fatty acid profiles. Examples of proposed product re-formulations that are currently undergoing product performance and stability testing can be found in Appendix A2.

Point 3: Care is needed to avoid unintended consequences.

As we move forward, it is absolutely essential that we take great care to avoid unintended consequences. Finding appropriate substitute ingredients to replace those that contain trans fat presents significant technological challenges that need to be overcome. That takes time, dedication, and patience. If companies are compelled to eliminate trans fat before a better substitute is developed—so that significantly higher levels of saturated fat (such as from tropical oils) are used instead—it would be a major step back for public health and an enormous disservice to American consumers. A relevant case study on reduction of trans fat in pot pie crust formulations can be found in Appendix A3. This case study illustrates the difficulties in product reformulation for the entire category of baked goods.

There is the distinct possibility of being confronted with the unintended consequence of companies removing trace amounts of partially hydrogenated oils (<0.5 g) and substituting an alternative ingredients that have higher levels of saturated fats than the original formulation simply to avoid the term "partially hydrogenated oils" from appearing in the ingredient listing. This is just one of the possible unintended consequences of rash actions against trans fat.

In conclusion, we need to keep our eye on the goal—to reduce trans fat in the diet while creating healthier products for consumers—even if it takes a little longer to get it right. The food industry will continue to address this issue seriously and in a responsible way. We urge the FDA to develop and support policies that achieve this goal and not to pursue directions that single-mindedly target trans fat.

We would be happy to meet with you further to discuss this if you would find that useful.

Sincerely yours,

Alison Kretser

Alison Kretser, MS, RD

Appendix A1
Examples of GMA Member Company Efforts to Reduce or Eliminate Trans Fat

Campbell Soup
Campbell Soup's Pepperidge Farm division announced in November 2003 that Goldfish® crackers will be transitioning its entire cracker product line to become free of trans fatty acids. More than 90 percent of the Goldfish® cracker line will be transitioned to zero trans fat by May 2004, with the remainder of the line converting by late summer. Goldfish® will provide consumers with the first line of zero trans fat crackers from a major brand. To lead off the transition to zero trans fat, Goldfish® is adding a brand new offering to the line – Goldfish Crisps®, which will be available nationally in March in three varieties: Cheddar Jack, Four Cheese and Cheesy Sour Cream & Onion. Then, over the next few months, all existing varieties of Goldfish® snack crackers will be converted to zero trans fat recipes.

ConAgra Foods
ConAgra Foods is actively applying the latest lipid technology to their portfolio of products including spreads, snacks, frozen meals, dairy, potato products and meal kits. They are testing product formulations for a wide array of functional properties to meet consumer needs for stability and overall acceptance.

The J.M. Smucker Company
The J.M. Smucker Company has introduced a new specially-formulated Crisco® All-Vegetable Shortening with zero grams trans fat per serving and no increase in the level of saturated fat. The specially-formulated Crisco® All-Vegetable Shortening tastes and performs well in a variety of classic Crisco® recipes.

Kraft
Kraft is reformulating a number of its product lines. They will introduce Triscuit® crackers with zero grams trans fat, the first in a series of biscuit products that will be reformulated to have zero grams or reduced levels of trans fat. Additionally, Nabisco will launch a four-item line featuring 100-calorie packs of the Wheat Thins®, Chips Ahoy!®, Cheese Nips® and Oreo® brands. These portion-control, single-serve snacks are formulated to have three grams or less of total fat, zero grams of trans fat and no cholesterol.

Monsanto
Monsanto unveiled a three-phase soybean breeding project last fall.

Phase 1: Using conventional breeding to produce a soybean with lower levels of linolenic acid. A low-linolenic soy oil would require less or no hydrogenation and could reduce or eliminate trans fat in many foods. The beans will be available to plant in two years.

Phase 2: Applying further conventional breeding to make this new bean higher in heart-healthy monounsaturated fats, producing a soy oil similar to olive oil but with a milder taste. Seed will be available in four to five years.

Phase 3: The soybean is further altered to bring its saturated fat down to one percent. It would be stable without hydrogenation, high in heart-healthy monounsaturated fats and almost free of saturated fats. Seed will be available in eight years.

PepsiCo

PepsiCo was the first major food company to eliminate trans fats from an entire product, namely Frito-Lay™ snacks, eliminating 50 million pounds of trans fats from the American diet, well in advance of the FDA labeling mandate. It has announced its commitment that 50 percent of new products will comprise essentially healthy ingredients or offer improved health benefits.

Unilever Bestfoods

Unilever Bestfoods North America announced the entire line of "I Can't Believe It's Not Butter!"® soft spreads will be free of trans fat, targeted for completion in the first half of 2004. Other products in Unilever Bestfoods portfolio of products that are already trans fat-free include all varieties of Promise®, Take Control®, Brummel & Brown® and Shedd's Country Crock Light®, to name just a few. Less than one half of one percent of American adults' total calories comes from the trans fat present in margarine products.